UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,348	09/26/2001	Wolfram Steinhilber	24702	2818

20529 7590 06/22/2004

NATH & ASSOCIATES
1030 15th STREET
6TH FLOOR
WASHINGTON, DC 20005

EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,348	STEINHILBER ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-16-01 & 1-24-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-17 are pending and have been considered on the merits in this Office Action.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/EP00/00324, filed 1/18/2000 or Application No. 60/155,268, filed 1/19/1999. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during

the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Information Disclosure Statement

Reference AU of the IDS filed January 24, 2003 contains an inaccurate reference to the page numbering which has been corrected on the Form 1449. The Van Golde reference spans only pp. 77-78. If Applicant would like to have the additional

references spanning pages 79-364 considered, these references should be listed individually on the Form 1449.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the limitation "at least substantially the same as" or "which is the same as" in Claims 1-17 are not clear. How similar must the protein be to be considered "substantially the same" as recombinant SP-A? Moreover, what similarities must the protein have to be considered the "same" (e.g. must they have the same sequence? The same function and if so what function must be the same?). Clarification is required.

Claims 1-4 are indefinite because the claims are drawn to a method but there are no method steps and no endpoint for one to know when the method has been

successfully practiced. If the claims were intended to be drawn to a method, including the steps of the method and an endpoint is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5-11 and 16-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Borron et al. (Am. J. Physiol. (Oct. 1998) 275(Lung Cell. Mol. Physiol. 19): L679-L686).

Borron et al. teach a composition comprising a recombinant SP-A that is identical to the composition presently claimed. The composition of Borron et al. is purified and the final preparation is lipid-free and contained in a buffer (considered a carrier) at neutral pH (p. L680, Col. 2, last two paragraphs). Thus, the composition of Borron et al. appears to be identical to a lipid-free medicament composition of the claims. The presently claimed methods of making the medicament (claims 1-3) are only limited to the composition used in the method and do not contain any method steps. Thus, Borron et al. is considered to meet the limitations of these claims. The examiner notes that the claims are drawn to a product with an intended use. However, without evidence that the intended use changes the product, the intended use is not considered because it is the product being claimed and not the method of using it. Therefore, while Borron et al. does not use the disclosed composition in a method of treatment, absent evidence to the contrary, the disclosed composition is identical to the composition presently claimed.

The recombinant SP-A in the composition of Borron et al. is considered "substantially the same" or the "same" as recombinant SP-A obtainable by expression of a genomic sequence or by expression of a cDNA coding for SP-A. Claims 16 and 17 are also anticipated by Borron et al. because the instructions and packaging of a composition is not considered to patentably distinguish the compositions over the prior art. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is

immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art.

Claims 1-3, 5-11, 13-14, and 16-17 are rejected under 35 U.S.C. 102(a) as being anticipated by LeVine et al. (J. Resp. Crit. Care Mol. Care Med. (1998) 157: A865; ref. AS of IDS filed 1-24-03).

LeVine et al. teach a method of treating a pulmonary infection in a mouse by administering SP-A. The SP-A in the composition disclosed in LeVine et al. is considered "at least substantially the same as recombinant SP-A" and since it appears to have the same function as recombinant SP-A it is considered "the same as" recombinant SP-A. Thus, LeVine is considered to meet the limitations of Claims 5-11. The presently claimed methods of making the medicament (claims 1-3) are only limited to the composition used in the method and do not contain any method steps. Thus, LeVine et al. is considered to meet the limitations of these claims. LeVine et al. indicate that 50-150 μg of SP-A. This amount of SP-A administered in LeVine et al. is considered an "effective amount" since it is the same as the amount taught in the instant Application (see p. 6, 2nd to last paragraph of the present Specification) and since LeVine et al. teach that the amounts administered therein were effective in enhancing bacterial clearance in the mouse. Thus, the LeVine et al. meets the limitations of Claims 13-14. Claims 16 and 17 are also anticipated by LeVine et al because the instructions and packaging of a composition is not considered to patentably distinguish the compositions over the prior art. In the Opinion Text of *In re Haller*, 73 USPQ 403

(CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art.

Claims 1-4 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kido et al. (EP 0 652 011; ref. AL of IDS filed 10-16-01).

Kido et al. teach a method of treating pulmonary viral infection with lung surfactant. Lung surfactant, which contains SP-A and SP-D, is disclosed by Kido et al. to be effective to treat the pulmonary viral infection. Thus, since the SP-A of the surfactant has the same sequence as recombinant SP-A and has the same function as recombinant SP-A, it is considered substantially the same as recombinant SP-A and the method disclosed therein is considered to meet the limitations of Claims 13-15. The methods of Claims 1-4 do not contain any method steps, therefore for the same reasons as given for Claims 13-15, the method of making the medicament of Claims 1-4 is anticipated by Kido et al. The examiner notes that the composition of Kido et al. is not lipid-free.

Claims 1-3 and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Schilling et al. (U.S. Patent No. 5,840,527; ref. AA of IDS filed 10-16-01).

Schilling et al. disclose the recombinant production of SP-A for use as a medicament (Col. 2, lines 39-55 and paragraph bridging Col. 6-7). Schilling et al.

discuss administration of the SP-A protein (Col. 8, lines 40-68). Thus, Schilling et al. is considered to teach a method of making a medicament composition for treating pulmonary infection or inflammation comprising a carrier and recombinant SP-A. Claims 16 and 17 are also anticipated by Schilling et al. because the instructions and packaging of a composition is not considered to patentably distinguish the compositions over the prior art. In the Opinion Text of *In re Haller*, 73 USPQ 403 (CCPA 1947), the court stated "Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned." The instructions of the instant kit are not considered to distinguish the claimed kits over the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormack et al. (J. Biol. Chem. (1994) 269(8): 5833-5841) and Borron et al. (Am. J. Physiol. (Oct. 1998) 275: L679-L686) in view of Madan et al. (Clin. Exp. Immunol. (1997) 110: 241-249; ref. AT of IDS filed 1-24-03), LeVine et al. (Am. J. Respir. Crit. Care Med. (1998) 157: A865; ref. AS of IDS filed 1-24-03), King et al. (Am. J. Respir. Crit. Care Med. (1995) 151: 1989-1997; ref AT of IDS filed 1-24-03), and Schilling et al. (U.S. Patent No. 5,840,527; Ref. AA of IDS filed 10-16-01).

McCormack et al. and Borron et al. provide evidence that at the time of the invention, recombinant production of SP-A was routine in the art. Moreover, Borron et al. provide evidence that the recombinant SP-A was functionally similar to SP-A purified from nature and is similarly effective in inhibiting T lymphocyte proliferation.. This evidence suggests that the recombinant form of SP-A would be equally effective in protecting against pathogens entering the lungs.

McCormack et al. and Borron et al. do not teach the use of recombinant SP-A in vivo.

Madan et al., LeVine et al., King et al., and Schilling et al. provide evidence that those of skill in the art at the time of the invention were well aware that SP-A could be effective in protecting or treating against various lung infections or disorders. Madan et al. teach that SP-A and SP-D are involved in the initial protective immunity against A. fumigatus (p. 242, Col. 1, 2nd paragraph and p. 248, Col. 1, last paragraph). Based on

the ability of these surfactant proteins to reduce histamine release by sensitized cells on allergen exposure, Madan et al. suggest that SP-A and SP-D may be used therapeutically in the treatment of allergic disorders such as allergic bronchopulmonary Aspergillosis (p. 248, Col. 1, last paragraph). LeVine et al. teach that an SP-A composition (that does not contain lipids) administered to mice enhances the pulmonary clearance of Group B Streptococcus. LeVine et al. does not teach the source of the SP-A. Wang et al. teach and provide evidence that SP-A and SP-D are able to suppress allergen-induced lymphocyte proliferation and histamine release in asthmatic children (p. 517, Col. 1, last paragraph). King et al. indicate that the functions of SP-A include modulation of the immune response, regulation of surfactant metabolism affecting surfactant secretion, mitigation of the effects of inhibitors of surfactant function, and reduction of superoxide production by alveolar macrophages (p. 1996, Col. 2, last paragraph). King et al. teach that SP-A is reduced in infants with hyaline membrane disease, and patients with acute respiratory distress syndrome. Schilling et al. suggest that recombinant SP-A could be used in the treatment of respiratory distress syndrome and related respiratory disease such as pneumonia and bronchitis (Abstract; Col. 2, lines 33-39; Col. 7, lines 57-63).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to make a medicament containing recombinant SP-A and a suitable carrier and to use that medicament in a method of treating a pulmonary infection or inflammation. McCormack et al. and Borron et al. provide evidence that recombinant production of SP-A was routine at the time of the invention and Madan et

al., LeVine et al., King et al., and Schilling et al. all provide evidence that those of skill in the art were aware that SP-A would be effective in treating pulmonary infections and disorders. Madan et al. suggests that SP-A could be used therapeutically and Schilling et al. suggests using the recombinant form of SP-A in treatments for respiratory distress, pneumonia, and bronchitis. The references also indicate that SP-D would also be effective. Therefore, one of ordinary skill in the art would have been motivated to make and use medicament compositions containing recombinant SP-A (with or without SP-D) for use in methods of treatment because recombinant technology would allow an easier method for obtaining large amounts of protein, a more purified form of the protein, and an easier way to modify the protein as necessary for the needs at hand.

Conclusions

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
June 19, 2004

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600